

**STATE OF CALIFORNIA  
OFFICE OF ADMINISTRATIVE LAW**

In re:	)	
	)	
EMERGENCY MEDICAL SERVICES	)	DECISION OF DISAPPROVAL
AUTHORITY	)	OF REGULATORY ACTION
	)	
	)	(Gov. Code, sec. 11349.3)
REGULATORY ACTION:	)	
Title 22, California Code of	)	
Regulations	)	OAL File No. 2009-0126-03S
	)	
ADOPT SECTIONS 100101.2, 100102.1,	)	
100102.2, 100103.1, 100106.1,	)	
100106.2, AND 100107.1	)	
AMEND SECTIONS 100101, 100102, 100103,	)	
100105, 100106, 100107, 100108, 100109,	)	
100111, 100112, 100113, 100114, 100115,	)	
100116, 100117, 100118, 100119, 100120,	)	
100121, 100122, 100123, 100124, 100125,	)	
100126, 100127, 100128, 100129,	)	
AND 100130	)	
_____	)	

**SUMMARY OF REGULATORY ACTION**

The Emergency Medical Services Authority proposed to amend Title 22 of the California Code of Regulations pertaining to Emergency Medical Technician II (EMT-II) training, certification, medical control, and scope of practice and also adding the Advanced Emergency Medical Technician classification.

**DECISION**

On March 11, 2009, the Office of Administrative Law disapproved the above referenced regulatory action for the following reasons: failure to make changes to the regulations available to the public; failure to include an adequate response to all public comments; failure to include all required documents in the rulemaking file; defective statement of mailing; and failure to comply with the "clarity" standard of Government Code section 11349.1.

## DISCUSSION

The adoption of regulations by the Emergency Medical Services Authority (“EMSA”) must satisfy requirements established by the part of the California Administrative Procedure Act (“APA”) that governs rulemaking by a state agency. Any rule or regulation adopted by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage. (Gov. Code, sec. 11346.)

Before any rule or regulation subject to the APA may become effective, the rule or regulation is reviewed by the Office of Administrative Law (“OAL”) for compliance with the procedural requirements of the APA and for compliance with the standards for administrative regulations in Government Code Section 11349.1. Generally, to satisfy the standards a rule or regulation must be legally valid, supported by an adequate record, and easy to understand. In this review OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of rules and regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on rules and regulations before they become effective.

### **1. THE REGULATIONS SUBMITTED TO OAL FOR FILING WITH THE SECRETARY OF STATE CONTAIN CHANGES THAT WERE NOT MADE AVAILABLE TO THE PUBLIC.**

Subdivision (c) of Government Code section 11346.8 requires that substantial changes to the original text be made available to the public for comment before the changes are adopted:

No state agency may adopt, amend, or repeal a regulation which has been changed from that which was originally made available to the public pursuant to section 11346.5, unless the change is (1) nonsubstantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. *If a sufficiently related change is made, the full text of resulting adoption, amendment, or repeal, with the change clearly indicated, shall be made available to the public for at least 15 days before the agency adopts, amends or repeals the resulting regulation.* Any written comments received regarding the change must be responded to in the final statement of reasons required by Section 11346.9. (Emphasis added.)

Section 44 of Title 1 of the California Code of Regulations (“CCR”) specifies how such sufficiently related changes are to be made available:

(a) At least 15 calendar days prior to the adoption of a change to a regulation required to be made available to the public by Government Code section 11346.8(c), the rulemaking agency shall mail a notice stating the period within which comments will be received

together with a copy of the full text of the regulation as originally proposed, with the proposed change clearly indicated, to the following:

- (1) all persons who testified at the public hearing; and
  - (2) all persons who submitted written comments at the public hearing; and
  - (3) all persons whose comments were received by the agency during the public comment period; and
  - (4) all persons who requested notification from the agency of the availability of such changes.
- (b) The rulemaking record shall contain a statement confirming that the agency complied with the requirements of this section and stating the date upon which the notice and text were mailed and the beginning and ending dates for this public availability period.

As discussed below, the text of the regulations submitted to OAL for filing with the Secretary of State in this rulemaking contained changes from the texts that were made available to the public during the initial 60 day and subsequent 15 day comment periods.

In subsection (b) of section 100113, the requirement that an eligible training program verify that the course content is equivalent to the Model Advanced EMT Standard Curriculum (EMSA #133, February 2007) was changed without notice to the public from the February 2007 version of EMSA #133 to the June 2007 version of EMSA #133. Similarly, in subsection (b) of section 100119, the requirement that an Advanced EMT trainee must demonstrate competency as specified in the model curriculum EMSA #133, dated February 2007, was changed without notice to the public to the June 2007 version of EMSA #133. In subsection (e) of section 100119, the same thing was done as to the requirements for documentation of student evaluations. In subsection (a) of section 100120, the same thing was done as to the content requirements of the Advanced EMT course itself.

In subsection (b) of section 100119, the requirement of students performing an “esophageal tracheal airway insertion” was changed to a “perilaryngeal airway adjunct insertion” without being made available to the public.

In section 100130, changes authorizing fees for Advanced EMT training programs, certification, and recertification were made after the public availability periods ended.

In subsection (a)(3) of section 100118, the Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care were identified as the 2005 version from the American Heart Association after the public availability periods ended.

In subsection (a) of section 100106.1, the following language was removed from the text as made available to the public:

Topics of instruction shall, at least, be equivalent to the relevant topics contained in the United States Department of Transportation's EMT-Intermediate National Standard Curriculum, DOT HS-809016, December 1999.

In subsection (b)(2) of section 100106.1, "Perform synchronized cardioversion and defibrillation" replaced the text made available to the public which provided:

Perform the following Optional Skill:

- (A) Cardiovert an unconscious patient in ventricular tachycardia
- (B) Defibrillate a patient in ventricular fibrillation.

Although one might argue that some of these changes may be considered "nonsubstantial", this does not appear to be true of all of the changes. For this reason, the substantive changes described above must be made available for comment pursuant to Government Code section 11346.8(c) and section 44 of Title 1 of the California Code of Regulations. Since the text must go out for at least a 15 day public availability period for the substantive changes, OAL recommends that any of the other changes listed above which arguably may be considered nonsubstantial should also be made available for public comment at the same time.

Also, subsection (a)(3) of Government Code section 11346.2 provides:

The agency shall use *underline or italics* to indicate additions to, and *strikeout* to indicate deletions from, the California Code of Regulations. (Emphasis added.)

In this way a member of the public reading the text of the regulation being made available to the public would understand what changes are being proposed by this rulemaking. Subsection (b)(6) of existing section 100106 provides for the administration of a specified list of drugs within the EMT-II scope of practice. This rulemaking revises this list and provides that all but 50% dextrose be administered in a route other than intravenous. The words "Intravenous administration of" were added in front of the existing subsection (b)(6)(I) by this rulemaking (now (b)(7)) to distinguish 50% dextrose from the other substances on the list. This new language was neither underlined nor italicized in the initial regulation text that was made available to the public during the 60 day comment period. As a result, a member of the public reading the initial text made available during the 60 day comment period would not have easily understood that this language was being added and was subject to public comment. For this reason, this new language also needs to be made available to the public for at least 15 days pursuant to Government Code section 11346.8(c) and section 44 of Title 1 of the California Code of Regulations.

**2. THE FINAL STATEMENT OF REASONS DOES NOT CONTAIN AN ADEQUATE RESPONSE TO ALL OF THE COMMENTS SUBMITTED DURING THE PUBLIC COMMENT PERIOD.**

Since its inception in 1947, the APA has afforded interested persons the opportunity to participate in quasi-legislative proceedings conducted by state agencies. The APA currently

requires that rulemaking agencies provide notice and at least a 45-day comment period prior to adoption of a proposed regulatory action. (Gov. Code, secs. 11346.4 and 11346.5). By requiring the state agency to summarize and respond in the record to comments received during the comment period, the Legislature has clearly indicated its intent that an agency account for all relevant comments received, and provide written evidence of its meaningful consideration of all timely, relevant input. Section 11346.9(a)(3) of the Government Code requires that the adopting agency prepare and submit to OAL a final statement of reasons which shall include:

A summary of each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reason for making no change....

The summaries and responses to the comments submitted during this rulemaking action are contained in two tables in the rulemaking file. On page 2 of the Summary of Comments Table for the 60 day comment period, the EMSA response to the second comment acknowledges the comment and states that this subsection "...has been amended to reflect Advanced EMT". No change appears to have been made to the regulation. Similarly on page 5 of the Summary of Comments Table for the 60 day comment period, for the first and second comments stating that non-intravenous drug administration should count as an Advance Life Support procedure, the EMSA response acknowledges the comments and states that the regulations will now read "intravenous fluids and /or medication specified in Section 100106(b) of this Chapter." (Emphasis added.) This change was not made to the regulations. In the Summary of Comments Table for the 15 day comment period, the third comment listed on page 3 proposes that suggested time frames/hours for additional instruction be added to section 100106.1. The EMSA response states that the regulations will be amended to include hours of instruction. This change was not made.

For this reason these responses to the comments are inadequate. If any revisions to the text of regulations are made in response to these comments, the changes to the regulation text should be made available for public comment for at least 15 days pursuant to Government Code section 11346.8(c) and section 44 of Title 1 of the California Code of Regulations as discussed above.

### **3. THE RULEMAKING FILE DOES NOT INCLUDE A COPY OF ALL OF THE REQUIRED DOCUMENTS.**

Subdivision (b)(7) of Government Code section 11347.3 requires that the rulemaking file include:

All data and other factual information, technical, theoretical, and empirical studies or reports, if any, on which the agency is relying in the adoption, amendment, or repeal of a regulation....

The Initial Statement of Reasons for this regulatory action identifies the following as technical, theoretical, and/or empirical studies, reports or documents relied upon in this rulemaking:

- information from the Imperial County EMT-I Advanced trial study which was duplicated in four counties in California,
- draft documents from the National EMS Scope of Practice Model for Advanced EMTs, and
- input from the EMT-II Task Force which consisted of California EMS constituents.

None of these documents were included in the rulemaking file as required by subdivision (b)(7) of Government Code section 11347.3. These documents must also have been available to the public during the public comment period.

The Initial Statement of Reasons for this regulatory action also identifies two documents that were incorporated by reference by these regulations:

- Advanced EMT Model Curriculum, February 2007, and
- EMT-II Skills Competency Verification Form.

Neither the rulemaking file nor the regulation text submitted with this rulemaking contained any copies of these incorporated documents, nor was the June 2007 version of the former included. Subsection (b) of section 20 of title 1 of the California Code of Regulations provides in pertinent part:

Material proposed for “incorporation by reference” shall be *reviewed in accordance with procedures and standards for a regulation* published in the California Code of Regulations.... (Emphasis added.)

In order to be reviewed by OAL, a document incorporated by reference must be included along with the regulation text submitted to OAL with the rulemaking file. The incorporated documents must also have been available to the public during the public comment period.

#### **4. CLARITY**

The Legislature in establishing OAL, found that regulations, once adopted, were frequently unclear and confusing to the persons who must comply with them. (Gov. Code, sec. 11340(b).) For this reason, OAL is mandated to review each regulation adopted pursuant to the APA to determine whether the regulation complies with the “clarity” standard. (Gov. Code, sec. 11349.1(a)(3).) “Clarity” as defined by Government Code section 11349(c) means “written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.”

Subsection (a)(1) of new section 100106.1 provides as an optional skill the administration of a list of medications. Within that list, subsection (a)(1)(G) provides: “Benzodiazepines (midazolam)”. A commenter questioned whether the intent was the administration of just midazolam. EMSA responded that midazolam was just an example of benzodiazepines. This should be clarified.

Subsection (e) of new section 100106.2 provides that:

The Director of the EMS Authority shall render the decision to approve or disapprove the trial study within forty-five days of receipt of *all materials specified in subsections (a) and (b) of this section*. (Emphasis added.)

A person directly affected by this regulation would not easily understand when the 45-day time period begins as no materials are specified in subsection (b) of section 100106.2.

Subsection (a) of new section 100107.1 provides:

The local EMS agency shall establish a system-wide continuous quality improvement program *as defined in Section 100102.1 of this Chapter*.

The Emergency Medical Services Quality Improvement Program is defined in section 100102.2.

We also note that the statement of mailing for the notice of proposed regulatory action in tab 3 of the rulemaking file is defective. Section 86 of title 1 of the California Code of Regulations requires that the rulemaking record contain a statement confirming that the agency complied with the provisions Government Code section 11346.1(a)(1) through (4) regarding the mailing of notice of proposed action at least 45 days prior to the public hearing or close of the public comment period. The statement of mailing included in the rulemaking file instead refers to the 15-day notice period for modified text.

Lastly we note that the text of the regulations submitted for filing with the Secretary of State contains some errors in showing changes to the text currently printed in the California Code of Regulations and that the STD 400 submitted with the text of the regulations omitted section 100106.2 from the list of sections being adopted and omitted section 100115 from the list of sections being amended.

**CONCLUSION**

For the reasons set forth above, OAL has disapproved this regulatory action. If you have any questions, please contact me at (916) 323-6808.

Date: March 18, 2009

**CRAIG TARPENNING**

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